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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,033	10/27/2003	David E. Berg	4425-PA1C2	3893

45848 7590 09/02/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/02/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID E. BERG, LOIS HILL BERG, and HAROLD H. HARRISON

Appeal 2008-3650
Application 10/694,033
Technology Center 1600

Decided: September 2, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a diagnostic method for coagulation response which the Examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm in part and enter a new ground of rejection.

Statement of the Case

The Claims

Claims 70-87 are on appeal. We will focus on claim 70, which is representative and reads as follows:

> 70. An ex vivo diagnostic method comprising steps of:
> identifying conditions that each cause a low level activation of the coagulation response in blood;
> providing a blood sample taken from a subject;
> providing different blood tests that are each for identifying low level activation of the coagulation response in blood;
> performing each of the different blood tests on the blood sample; and
> if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the-at least two of the blood tests to assist in diagnosing the subject with one of the conditions.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Maxwell M. Wintrobe et al., *Approach to Patients with Bleeding Disorders*, Clinical Hematology 7th ed. (Philadelphia, Lea & Febiger) 1048-1070. RB 145.W73. (1974).

Jens V. Sorenson et al., *Markers of Coagulation and Fibrinolysis after Fractures of the Lower Extremities*, 65 THROMBOSIS RESEARCH 479-486 (1992).

The issues

The rejections as presented by the Examiner are as follows:

A. Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as anticipated by Wintrobe (Ans. 5).

B. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as anticipated by Sorensen (Ans. 7).

A. 35 U.S.C. § 102(b) anticipation rejection over Wintrobe

Appellants argue that

> Wintrobe et al. are concerned with the study of hemostasis, e.g., the stoppage of bleeding, and blood coagulation and blood clotting defects. In Appellants' claim 70, the method is not directed to stopping bleeding, the study or science of blood coagulation, or tests merely for determining coagulation abnormalities that bleeding patients may have. Quite to the contrary, Appellants' method set forth in claim 70 is concerned first with identifying conditions that each cause a low level activation of the coagulation response in blood.

(App. Br. 14.) Appellants further contend that the "four tests identified in Table 33-3 are not tests for identifying low level activation of the coagulation response in blood" (App. Br. 15).

Appellants argue that "Wintrobe et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject" (App. Br. 16).

The Examiner responds that "it is submitted that this step [identification conditions] may be considered a mental step, such conditions

which cause low coagulation response levels in blood were known in the art, and furthermore are clearly set forth by Wintrobe et al in at least Tables 33-2 and 33-3" (Ans. 9). The Examiner further argues that "these four primary blood tests, along with the other blood tests disclosed by Wintrobe et al (including tests for fibrinogen levels, platelet activation levels and fibrin-fibrinogen degradation product levels) are, indeed, each standard tests for assaying the coagulation response in blood" (Ans. 9).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the disclosure of Wintrobe teach a diagnostic method to identify low level activation of the coagulation response in blood?

Findings of Fact (FF)

1. Wintrobe teaches that the "initial laboratory study of the bleeding patient should be guided by the information obtained from the clinical evaluation. However, the routine use of a small battery of screening tests has merit in many cases, since it serves to direct the course of further study and usually saves time" (Wintrobe 1062, col. 2).

2. Wintrobe teaches obtaining a blood sample from patients, noting "[b]lood samples obtained by means of traumatic venipunctures or from indwelling catheters often are inadequate for coagulation studies. Even the small amounts of heparin used to flush indwelling catheters can produce marked coagulation abnormalities" (Wintrobe 1056, col. 1).

3. Wintrobe discloses different blood tests including platelet count, bleeding time, partial thromboplastin time, plasma prothrombin time,

coagulation time, throboplastin generation test, plasma thrombin time, and fibrinogen assay (Wintrobe 1050, table 33-2).

4. The Specification teaches "tests which can detect minimal activation of the coagulation response in a patient . . . tests for determining levels of fibrinogen, prothrombin fragment 1 + 2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation by flow cytometry" (Spec. 2:3-6).

5. Wintrobe teaches performing multiple blood tests noting that "most essential information can usually be obtained from four tests summarized in Table 33-3, which in view of their availability, simplicity and low cost, are admirably suited to serve as 'primary' screening tests" (Wintrobe 1062, col. 2).

6. Wintrobe discloses that when the two assays for prothrombin time and the partial throboplastin time are prolonged, but the bleeding time and platelet count assays are normal, several possible presumptive diagnoses including deficiencies in factors V, X, liver disease or vitamin K deficiency are possible diagnoses (*see* Wintrobe 1063, Table 33-3, line E).

A. Discussion of 35 U.S.C. § 102(b) anticipation rejection over Wintrobe

We conclude that the Examiner has set forth a prima facie case that claim 70 is anticipated by Wintrobe. Wintrobe teaches an ex vivo diagnostic method to identify conditions that cause low level activation of the coagulation response (FF 1, 6) including performing specific tests for coagulation response on blood from patients (FF 2, 3). Wintrobe teaches performance of multiple tests on the samples (FF 5) and using the results of

the tests to assist in the diagnoses of the subject (FF 6), including tests which the Specification suggests are functional (*see* FF 3, 4).

We are not persuaded by Appellants argument that "the method is not directed to stopping bleeding . . . or tests merely for determining coagulation abnormalities that bleeding patients may have" (App. Br. 14). Appellants' claim 70 expressly encompasses identifying any "conditions that each cause a low level activation of the coagulation response in blood".

In analyzing claim 70, our mandate is to give the claim its broadest reasonable interpretation.

> Giving claims their broadest reasonable construction 'serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.' *Yamamoto*, 740 F.2d at 1571; accord *Hyatt*, 211 F.3d at 1372; *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989) ('An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.').

In re American Academy of Science Tech Center, 367 F.3d 1359, 1364, (Fed. Cir. 2004). In our opinion, the reasonable interpretation of the claimed "conditions that each cause a low level activation of the coagulation response" encompass many, if not all, of the conditions listed by Wintrobe in Table 33-3 (*see* FF 5, Wintrobe 1063). These conditions include von Willebrand's disease, thrombocytopenia, hemophilia A, among an extensive list of conditions that are associated with low level activation of the coagulation response (Wintrobe 1063, table 33-3). Consequently, we

conclude that Wintrobe teaches conditions which satisfy the scope of the claims (FF 5-6).

We are also not persuaded by Appellants argument that the "four tests identified in Table 33-3 are not tests for identifying low level activation of the coagulation response in blood" (App. Br. 15). In fact, all of the recited assays, such as bleeding time, function to provide information regarding the efficacy of coagulation (FF 3). Wintrobe notes that the "partial thromboplastin time measures all of the coagulation factors involved in the intrinsic and common pathways (Fig. 33-5) and is generally accepted as the best single screening test for disorders of blood coagulation" (Wintrobe 1062, col. 2). Thus, Wintrobe also suggests the other three tests in Table 33-3 as primary screening tests for blood coagulation deficiencies (FF 5). Most of the disorders of blood coagulation shown in Table 33-3 of Wintrobe represent low levels of activation of the coagulation response (*see* Wintrobe 1063, Table 33-3) and thereby satisfy this claim element.

We therefore affirm the 35 U.S.C. § 102(b) anticipation rejection of claim 70 as anticipated by Wintrobe. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 71, 72, 74-76 as these claims were not argued separately. We also affirm the rejection of claims 77-79 and 81-87 since pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), "[a] statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim."

B. 35 U.S.C. § 102(b) anticipation rejection over Sorenson

Appellants' argue that the Sorensen method "is for an entirely different purpose from the claimed invention set forth in claim 70 and

obtains results that are entirely different from Appellants' invention set forth in claim 70" (App. Br. 24). Appellants' further contend that Sorensen fails to teach "using the at least three of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood" (App. Br. 25).

The Examiner responds that "the step of identifying conditions which cause a low coagulation response in blood is considered to be a mental step, as such conditions were known in the art, thus 'identification' of such conditions merely requires identification from the knowledge available to one of ordinary skill in the art" (Ans. 11). The Examiner further argues that the "claimed method only requires the results to 'assist' in diagnosis, by providing a negative result, the method of Sorensen et al is considered to assist in diagnosis" (Ans. 11).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the disclosure of Sorensen teach a diagnostic method to identify low level activation of the coagulation response in blood?

Findings of Fact

7. Sorensen teaches that the "study comprised 28 patients with hip fractures . . . 5 with fractures of the femur shaft and 6 with tibial fractures" (Sorensen 480).

8. Sorensen teaches that "blood samples were taken from an antecubital vein immediately after admission and at 10 a.m. on the following day" (Sorensen 480).

9. Sorensen discloses performing the prothrombin fragment 1 and 2, thrombin/antithrombin III, fibrinogen and fibrin monomers diagnostic assays (Sorensen 480).

10. Claim 73 requires performance of at least three of "fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes and soluble fibrin monomer" (Claim 73).

11. Sorensen concluded that there was "substantial haemostatic activation as a[n] immediate response to trauma" (Sorensen 485).

B. Discussion of 35 U.S.C. § 102(b) anticipation rejection over Sorensen

We agree with Appellants that Sorensen fails to anticipate claim 70 because Sorensen does not teach the step of "identifying conditions that each cause a low level activation of the coagulation response in blood" (Claim 70). In order to anticipate, the prior art must teach all of the limitations of the claim. *See In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1371 (Fed. Cir. 2007). ("Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently.")

In this case, the Examiner contends that the limitation is satisfied not by the art, but by the "knowledge, inherent to the skilled artisan" (Ans. 7). While such knowledge may render the claim prima facie obvious, in the context of an anticipation rejection, the knowledge must be found in the cited prior art reference, either expressly or inherently. *See Id.* Sorensen teaches several of the active steps of claim 70 (FF 8-10), but Sorensen clearly fails to connect the coagulation response to any condition whatsoever (FF 7, 11).

We are not persuaded by the Examiner's argument that "because Sorensen et al did not identify low coagulation response, the information 'did' assist in diagnosis, as it steers one away from a diagnosis of conditions that cause a low coagulation response in blood" (Ans. 8). In fact, had Sorensen obtain low responses, Sorensen would not have correlated those to conditions with low coagulation response, but would have concluded that there was not immediate physiological haemostatic activation in response to trauma (*see* Sorensen 480). Thus, Sorensen provides the counterfactual example to the Examiner's argument.

We therefore reverse the 35 U.S.C. § 102(b) anticipation rejection of claims 70-87 as anticipated by Sorensen.

New Grounds of Rejection

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 73 and 80 are rejected under 35 U.S.C. § 103 as obvious in view of Wintrobe and Sorenson.

Wintrobe teaches an ex vivo diagnostic assay ("initial laboratory study of the bleeding patient should be guided by the information obtained from the clinical evaluation. However, the routine use of a small battery of screening tests has merit in many cases, since it serves to direct the course of further study and usually saves time" (Wintrobe 1062, col. 2)).

Wintrobe teaches obtaining a blood sample from patients, noting "[b]lood samples obtained by means of traumatic venipunctures or from indwelling catheters often are inadequate for coagulation studies. Even the

small amounts of heparin used to flush indwelling catheters can produce marked coagulation abnormalities" (Wintrobe 1056, col. 1).

Wintrobe discloses different blood tests including platelet count, bleeding time, partial thromboplastin time, plasma prothrombin time, coagulation time, throboplastin generation test, plasma thrombin time, and fibrinogen assay (Wintrobe 1050, table 33-2). Wintrobe teaches performing multiple blood tests noting that "most essential information can usually be obtained from four tests summarized in Table 33-3, which in view of their availability, simplicity and low cost, are admirably suited to serve as 'primary' screening tests" (Wintrobe 1062, col. 2).

Wintrobe discloses that when the two assays for prothrombin time and the partial throboplastin time are prolonged, but the bleeding time and platelet count assays are normal, several possible presumptive diagnoses including deficiencies in factors V, X, liver disease or vitamin K deficiency are possible diagnoses (*see* Wintrobe 1063, Table 33-3, line E).

Wintrobe does not teach performance of at least three of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes and soluble fibrin monomer.

Sorensen discloses performing the prothrombin fragment 1 and 2, thrombin/antithrombin III, fibrinogen and fibrin monomers diagnostic assays (Sorensen 480).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the three tests of Sorensen as confirmatory tests for coagulation response as desired by Wintrobe since Sorenson teaches that these tests represent "different clotting assays"

(Sorenson 479) and since Wintrobe states after primary screening to obtain a presumptive diagnosis, that diagnosis "can then be further clarified by the confirmatory methods summarized in the following section." (Wintrobe 1062).

In *KSR Int'l v. Teleflex*, the Supreme Court, in rejecting the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, indicated that

> The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

Applying the *KSR* standard of obviousness to Wintrobe and Sorensen, we conclude that the combination of additional confirmatory assays for coagulation response, as taught by Sorensen, with the diagnostic methods of Wintrobe, represents a combination of known elements which yield the predictable result of permitting additional confirmation of coagulation response in a variety of conditions. Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 1727 S. Ct. at 1740.

CONCLUSION

In summary, we therefore affirm the 35 U.S.C. § 102(b) anticipation rejection of claim 70 as anticipated by Wintrobe. Pursuant to 37 C.F.R. §

41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 71, 72, 74-76 as these claims were not argued separately. We also affirm the rejection of claims 77-79 and 81-87 since pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), "[a] statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim."

We reverse the 35 U.S.C. § 102(b) rejection of claims 70-87 over Sorensen.

Regarding the affirmed rejection(s), 37 C.F.R. § 41.52(a)(1) provides "Appellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the Examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have

> the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner....
>
> (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record....

Should the Appellants elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the Appellants elect prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED IN PART, 37 C.F.R. § 41.50(b)

LP

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